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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/645,447
Filing Date: August 20, 2003
Appellant(s): PURCELL, RICKY W.

Andrew R. Peret
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 26, 2007 appealing from the Office action mailed August 09, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,741,510	ROLF et al.	04-1998
4,592,358	WESTPLATE	06-1986
6,245,347	ZHANG et al.	06-2001

Copending Application S.N. 10/954,764, Publication number 2006/0067994, PURCELL.

(9) Grounds of Rejection

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following ground(s) of rejection are applicable to the appealed claims

Double patenting rejection:

Claims 32-43, 46, 47, 49-62 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/954,764 in view of US 5,741,510 (510). The subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: system and kit comprising holder, first exothermic patch (recited by claims 3 and 17 of the copending application), second endothermic

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patch (recited by claims 4 and 18 of the copending application), and third analgesic formulation.

The difference between the present claims the conflicting claims of the copending application is that the analgesic formulation instantly claimed is analgesic patch and the copending application recite the analgesic formulation as oral formulation.

US '510 teaches topical analgesic patch that has the advantage of providing excellent sustained release properties during the period of use and is more also comfortable and well tolerated by patients (abstract; col.1, lines 33-36, 47-50; col.2, lines 24-26).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide system for providing therapy to part of the body comprising holder, exothermic patch, endothermic patch, and analgesic formulation as claimed by the copending claims, and replace or select the topical analgesic patch formulation disclosed by US '510 as an analgesic formulation, motivated by the teaching of US '510 that topical analgesic patches are advantageous because they provide excellent sustained release properties during the period of use and are more comfortable and well tolerated by patients, with reasonable expectation of having system for providing therapy to part of the body comprising holder, exothermic patch, endothermic patch, and analgesic patch that successfully provides excellent sustained release properties during the period of use and are more comfortable and well tolerated by patients.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

Claims 40, 41, 43, 46, 47 stand rejected under 35 U.S.C. 102(b) as being anticipated by US 4,592,358 ('358).

Present claim 40 is directed to system comprising first patch, second patch and flexible wrap. Claim 41 is directed to third patch. Claim 43 requires enclosure for the patches, and claims 44-45 require container or board as a holder. Claim 46 recites more than one first patch. Claim 47 requires releasably attachment of the patches to the holder.

US '358 disclosed therapeutic device featuring a plurality of compartments enclosing a therapeutic substance which may be a refrigerant, which reads on endothermic patch, a heat releasing substance (which reads on exothermic patch), or a high density material or weighed packets (which reads on third patch), the device may be wrapped on various body portions using strap means (abstract; col.4, lines 20-25; col.5, lines 25-26). The reference disclosed that weight may be applied in combination with cooling or heating and the application of compression from the weight packet simultaneously with heating or cooling (col.4, lines 39-43). The device comprises packets that slide easily into compartments of the device, which reads on holder as a container (col.3, lines 1-4). Packets reads on patches claimed by applicants because applicant disclosed patch as "packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy", page 5, lines 11-12 of the present disclosure. The figures show holder that can read on

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board. The device comprises a plurality of compartments, but any number of compartments may actually be filled with cooling or heating packets or weights for any particular application. The reference disclosed that according to one embodiment wherein cooling or heating packets are removable, i.e. releasably attached (col.3, lines 6-20). A single therapeutic device may be used to cool or heat, simultaneously, two different, but spaced nearby body areas (col.3, lines 26-35). The device is wrapped around the bodily injury by strap means that encircle the therapeutic device (col.5, lines 50-53). The device is flexible, and this implies that the strap is flexible so it can be wrapped around and encircles areas of the body (col.5, lines 1, 10). The limitations of claims 40, 41, 43, 46, 47 are met by US '358.

Claim Rejections - 35 USC § 103

Claim 42 stands rejected under 35 U.S.C. 103(a) as being unpatentable over US '358 in view of US 6,245,347 ('347).

The teachings of US '358 are discussed under 102 rejection above.

Although US '358 disclosed third type of patch, however, it does not specifically teach an analgesic patch as claimed by claim 42.

US '347 teaches analgesic patch that can be advantageously administered along with exothermic heating or endothermic cooling means or devices to control the release and absorption of the analgesic according to the patient's need. The cooling or heating device can be applied directly to the skin and can be fixed by tape, adhesive or the like (abstract; col.5, lines 22-26; col.7, lines 35-39; col.8, lines 27-31; col.9, lines 18-31).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide system for providing therapy to part of the body comprising holder, exothermic packet, endothermic packet, and third packet to be provided to injured portion of the body as disclosed by US '358, and replace the third packet with or further add analgesic patch that advantageously accompanied with cooling or heating means as disclosed by US '347, motivated by the teaching of US '347 that it is advantageously to administer the analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic, with reasonable expectation of having system for providing therapy to part of the body comprising holder, exothermic packet, endothermic packet, and analgesic patch, wherein the system provides relief of the discomfort of the injured area and further provides controlled delivery of analgesic drug to relive the pain and be involved in the treatment of the injured part of the body, with successful relief of pain or discomfort of the patient.

(10) Response to Argument

(A) *The provisional rejection of claims 32-62 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of co-pending Application No. 10/954,764 in view of US 5,741,510.*

The examiner acknowledged that appellant will consider whether filing a Terminal Disclaimer is appropriate when all claims are indicated to be otherwise allowable and if

some overlap arises between the subject matter of the present application and the allowed claims of those other applications.

However, the “provisional” double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that “provisional” double patenting rejection is the only rejection remaining in one of the applications. If the “provisional” double patenting rejection in one application is the only remaining rejection in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other applicant into a double patenting rejection at the time the one application issues as a patent.

B) The Applicable Law under 35 U.S.C §102(b)

The examiner acknowledges and understands the law under 35 U.S.C §102(b) provided by appellant in the brief, and the law under 35 U.S.C §102(b) is applied to the claims rejected under anticipatory rejection as set forth in this examiner’s answer.

C) Discussion of the rejection of claims 40, 41, 43, 46 and 47 under 35 U.S.C. 102(b) as being anticipated by US 4,592,358.

Appellant argues that ‘358 does not teach or suggest “a container that includes at least one compartment” in combination with “wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container” as recited in claim 40. The therapeutic device 10 disclosed in ‘358 only describes cooling OR heating

packets (see '358 at col. 3, line 12, 27, 37). Therefore, '358 does not teach or suggest that the cooling OR heating packets are within the therapeutic device 10 at the same time such that disclosed therapeutic device 10 does not hold packets that apply different types of therapy as recited in claim 40. Appellant argues that '358 does not teach or suggest "a third patch held by said holder, wherein said third patch applies a third therapy..., the third therapy being different than the first and second therapies, wherein the first patch, the second patch, the third patch and the flexible wrap are all within the same compartment in the container" as recited in claim 41.

In response to this argument, appellant's attention is directed to the scope of the claims included in the anticipatory rejection that is directed to product and all the elements of the product are disclosed by '358. Claim 40 is directed to system comprising first patch, second patch and flexible wrap all in one container and US '358 disclosed three types of packets including heating, cooling and weight. Packets disclosed by the reference read on patches claimed by applicants because applicant disclosed patch as "packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy", page 5, lines 11-12 of the present disclosure. US '358 disclosed flexible wrap as part of the device, and device 10 of the reference itself reads on the container since all the other elements are contained in the device and the present claims recite the expression "comprising". Claim 41 is directed to third patch, and the weight packet reads on third patch. Claim 43 requires enclosure for the patches, and device 10 reads on the enclosure since the present claims recite the expression comprising" and in absence of any definition of the

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disclosure. Claim 46 recites more than one first patch, and the reference teaches cooling two parts of the body simultaneously (col.3, lines 26-35), i.e. more than one patch of the same kind are in the device. Claim 47 requires releasably attachment of the patches to the container, and the reference disclosed that the packets can be removed from the device, i.e. releasable. All the elements of the rejected claims are disclosed by US '358.

Appellant traverses the examiner statement at page 8 of the Final Office Action that “The container does not impart patentable weight with regard to 102 rejection absent functional relationship between the container and the product, and because the product still function equally effectively with or without the container.” Appellant argues that it cannot be seen why a functional relationship must be imparted between the container and the first and second patches in order to make claim 40 patentable. Appellant notes that claim 40 defines a structural relationship between the container and the first and second patches by reciting "wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container" which is not described in '358. Appellant further argues that the system would not function as effectively without a container. Appellant's spec. at page 8, lines 6-10, disclosed a container is required in order to “reduce the amount of therapy-related items that would otherwise need to be inventoried in order to provide the ability to apply different types of therapy to an injured portion of a body.” (See also Appellant's spec. at page 2 lines 22-26). Appellant argues that whether “the product still function equally effectively with or

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without the container” is not relevant to patentability as ‘358 must still describe “wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container” as recited in claim 40. Appellant argues that ‘358 teaches that the flexible wrap is the container instead of the flexible wrap being within the container wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container” as recited in claim 40.

In response to the arguments regarding the container, it is argued that the device 10 disclosed by US '358 itself is an inherent container containing different packets and a flexible wrap. In absence of claiming specific container, the device of US '358 is a container. The device 10 of the reference, inherently, containing all the claimed elements including packets and flexible wrap and functioning as container. According to applicant's disclosure in page 8, lines 6-10, the container is required to provide the ability to apply different types of therapy to an injured portion of a body, and US '358 disclosed device that is capable to provide different types of therapy to an injured part at col.4, lines 41-43, wherein the reference stated that: "... weight may be applied in combination with heating or cooling operations. This may be especially advantageous if compression to an injured area is desired while simultaneously heating or cooling the area". Therefore, US '358 clearly disclosed simultaneous application of different types of therapies to the injured portion of the body as desired by applicant's container. The prior art device is inherently containing the elements of the device and capable to perform the function as instantly claimed. Nothing in applicant's claims suggests that the container is of a different shape' than US '358, therefore, the device disclosed by the reference

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reads on the claimed container. See *In re Schreiber*, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997).

Appellant argues that the weight disclosed in '358 does not provide any type of therapy. Therefore, the weight is not a "a third patch held by said container, wherein said third patch applies a third therapy..., the third therapy being different than the first and second therapies" as recited in claim 41. In addition, Appellant argues that '358 not describe placing more than one packet (whether they are the same type or not) into the same compartment within a container as recited in claim 40.

In response to this argument, it is argued that the present claims are directed to system comprising 3 patches/packets, and US '358 disclosed device comprising three packets including heating, cooling and weight. The claims included in the rejection do not recite which type of therapy, and do not exclude any type of therapy. Weight is type of therapy that provides compression of the injured area to provide mechanical hemostasis. In page 5, lines 8-10, applicant disclosed that: "It should be noted that any type of patch may used in system 10 or any systems described herein. Some other example patches include infrared energy reflectors, antibiotic patches, electrical stimulating devices, and devices that deliver acupressure therapy." Therefore, devices providing pressure are within the scope of the present invention, and weight packets providing compression read on therapeutic patch instantly claimed. as such, US '358 disclosed device comprising three types of therapeutic patches/packets. Additionally, US '358 disclosed device that is capable to provide different types of therapy to an

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injured part at col.4, lines 41-43, wherein the reference stated that: "... weight may be applied in combination with heating or cooling operations. This may be especially advantageous if compression to an injured area is desired while simultaneously heating or cooling the area". Therefore, US '358 clearly disclosed simultaneous application of different types of therapies to the injured portion of the body

Appellant argues that the examiner statement at page 8 of the Final Office Action that "different therapies are applied at the same time is directed to the intended use that imparts no patentability to claims directed to product", while claim 40 defines a system where the system includes (i) a first patch that applies a first therapy; (ii) a second patch that applies a second therapy; and (iii) a flexible wrap where the first patch, second patch and flexible wrap are all within the same compartment in the container at the same time and the first therapy is different than the second therapy, and '358 only describes placing one type of packet within the therapeutic device at the same time (i.e., heating OR cooling packets).

In response to this applicant's argument, it is argued that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. US '358 described device comprising three different packets and disclosed simultaneous use of weight packet with cooling or heating pack (col.4, lines 39-43), therefore, the device disclosed by US '358 is capable

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of performing the claimed intended use of applying different therapies at the same time, and the disclosure of US '358 meets the rejected claims. The multiple packs of the prior art can be used to provide different therapies at the same time. For example, cold packs can be used in traumatically injured patient that is suffering from bruise, burn and bone fracture. Cold packs can be applied for these three different injuries to provide different therapies at different sites of the body at the same time.

D) The Applicable Law under 35 U.S.C. §103(a)

The examiner acknowledges and understands the law under 35 U.S.C §103(a) provided by appellant in the brief, and the law under 35 U.S.C §103(a) is applied to the claims rejected under obviousness rejection as set forth in this examiner's answer.

E) Discussion of the rejection of claim 42 under 35 U.S.C. 103(a) as being unpatentable over US 4,592,358 in view of US 6,245,347('347).

I. '358 and '347 do not teach or suggest every element of claim 42

Appellant repeats that '358 does not teach or suggest "a container that includes at least one compartment" in combination with "wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container" as recited in claim 40. Appellant further argues that '347 is not related to a holder or container that secures the disclosed patches. Therefore, Appellant argues that combination of '358 and '347 does not teach or suggest where first and second patches

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are within the same compartment in a container at the same time and are able to apply different types of therapy as recited in claim 40, and the combination of '358 and '347 does not teach or suggest a system as recited in claim 42.

In response to the argument against '358, the examiner hereby repeats the argument as set forth in this examiner's answer.

In response to the argument that the combination of '358 and '347 does not describe every element of the claimed invention as required by claim 40, it is argued that all the elements of claim 40 are disclosed by US '358, as set forth. US '347 is relied upon for the sole teaching of combination of analgesic patch with heating or cooling pad. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rationale to modify or to combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). In this case one having ordinary skill in the art at the time of the invention would have been motivated to provide system for providing therapy to part of the body comprising holder, exothermic packet,

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endothermic packet, and third packet to be provided to injured portion of the body as disclosed by US '358, and replace the third packet with or further add analgesic patch that advantageously accompanied with cooling or heating means as disclosed by US '347, motivated by the teaching of US '347 that it is advantageously to administer the analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic, with reasonable expectation of having system for providing therapy to part of the body comprising holder, exothermic packet, endothermic packet, and analgesic patch, wherein the system provides relief of the discomfort of the injured area and further provides controlled delivery of analgesic drug to relieve the pain and be involved in the treatment of the injured part of the body, with successful relief of pain or discomfort of the patient.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

II. Combining '358 and '347 would destroy the stated purpose '347

Appellant argues that combining '358 with '347 by altering the '358 to include a control apparatus 100 as disclosed in '347 would destroy the stated purpose of '347 which is the "administration of drugs." (See '347 at column 3, lines 54-56). Appellant notes that placing the apparatus 100 into the compartments 12 of '358 would not allow the apparatus 100 to deliver drugs because the apparatus 100 would not engage the skin and combining '358 with '347 would destroy the stated purpose of '347. Appellant argues that the only description as to placing an endothermic, exothermic and analgesic patch within the same compartment in a container is found Appellant's specification and claims. Appellant further argues that '358 does not include any description as to removing any of heating OR cooling packets in order to provide therapy. The therapeutic device 10 disclosed in '358 is meant to operate by inserting heating OR cooling packets into compartments 12 and then securing the therapeutic device 10.

In response to applicant's argument that placing the control apparatus 100 into the compartments 12 of '358 would not allow the apparatus 100 to deliver drugs because the apparatus 100 would not engage the skin, it is argued that '347 is relied upon for the sole teaching of analgesic patch and for teaching the combination of endothermic, exothermic and analgesic patch in one device. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The elements of the present claim 42 is taught by the combination of US '358 and US '347, which is device comprising three patches or packets including exothermic,

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endothermic and analgesic patch. One of ordinary skill in the art would have been able to determine which patch need to contact the skin directly and which patch can be applied within the device 10.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

(11) Related Proceeding(s) Appendix

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No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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